Remarks

Claim 31 is cancelled.

Claim Rejections 35 USC § 112

Applicants have cancelled claim 31, which renders this rejection moot.

Claim Rejections- 35 USC § 103

THE COMMERCIAL SUCCESS OF THE CLAIMED COMPOSITION RENDERS THE CLAIMS NON-OBVIOUS.

In response to the § 103 obviousness rejections put forth by the Office, Applicants present herein evidence of commercial success of the claimed composition. Commercial success abroad, as well as in the United States, is relevant in resolving the issue of nonobviousness. MPEP 716.03(II) citing *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). The claimed composition is available commercially in a number of countries throughout the world. Of those countries, the product has only been available for a sufficient amount of time in Brazil, Canada, and Switzerland to compile meaningful data. A declaration under Rule 132 is provided herewith which presents combined data for these three countries.

The declaration attests that "total quarterly sales of a topical ophthalmic solution containing 0.2% brimonidine by weight and 0.5% timolol by weight steadily and significantly increased, while the sales of brimonidine alone were roughly constant." Thus, the claimed composition did not merely cannibalize brimonidine sales, but created its own market. This is unequivocal evidence of independent commercial success.

This result demonstrates the claimed composition provides benefits beyond those provided by the Larsson (Arch Ophthalmol., Vol. 119, 2001, pp. 492-495), which was cited by Examiner. Examiner alleged that Larson teaches administration of 0.5% timolol topically followed by administration of 0.2% brimonidine five minutes later to the same eye. Carrying out the Larsson method presents no apparent difficulty. A physician need only prescribe both 0.5% timolol and 0.2% brimonidine to a patient, and instruct the patient to take a drop of the timolol, wait five minutes, and take a drop of the brimonidine. Thus, once the method was known, it must have been quickly adopted to help those in need of the method.

The earliest data presented in the declaration represents sales from Q4 2002. This is well over a year after Larsson's publication, so the sales of brimonidine at that time must reflect the use by those patients who were being treated by Larsson's method. If the claimed method provided no significant

benefit beyond Larsson, one would not expect that introduction of the claimed composition would increase the brimonidine sales. The only sales of COMBIGAN® would be to those individuals who were already purchasing brimonidine as part of the Larsson regimen. Thus, the sales of COMBIGAN® would be expected to be offset by a drop in brimonidine sales.

This is not what happened. What happened is that the brimonidine alone sales remained constant, while a new market was created for COMBIGAN®. Since the patients who used the Larsson method were already part of the brimonidine sales, the sales of COMBIGAN® must have arisen from patients who switched from another type of therapy. This indicates that the claimed method possesses some unexpected advantages beyond those provided by Larsson's method. This is the epitome of non-obviousness.

Double Patenting

The claim is provisionally rejected under the judicially created doctrine of double patenting over Application NO. 10/126,790, no US Patent Application No. 7,030,149. Applicants file a terminal disclaimer herewith. Thus, this rejection is overcome.

In light of the declaration submitted herewith and the arguments made herein, Applicants believe that the claim is patentable as it stands. Therefore, Examiner is respectfully requested to allow the claim.

Please charge Deposit Account 01-0885 for any fees related to this response.

Respectfully submitted,

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Rule 132 affidavit
Terminal Disclaimer